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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/610,891	07/06/2000	James McArthur	40567	6712

7590

01/30/2006

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EXAMINER

YU, MISOOK

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 01/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/610,891

Applicant(s)

MCARTHUR ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 February 2005 and 11 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 35-40 and 44-52 is/are pending in the application.
- 4a) Of the above claim(s) 48-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 35,37,38 and 40 is/are rejected.
- 7) ☒ Claim(s) 36,39 and 44-47 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 25 February 2005 and 11 July 2005 has been entered.

Claims 48-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) from the examination for reason of record. Claims 35-40 and 44-52 are pending. Claims 35-40 and 44-47 are examined on merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

This Office action contains new grounds of rejections.

### ***Specification, Maintained***

The specification remains objected because the trademark GVAX is not be accompanied by the generic terminology. It is not clear what the single bracket surrounding GVAX means in the amendment to the specification filed on 15 July 2005. Adding the generic terminology for the trademark GVAX at its first occurrence would obviate this objection.

***Claim Rejections - 35 USC § 103, Withdrawn***

The rejection of claims 35-39 and 44-47 under 35 U.S.C. 103(a) as being unpatentable over Sanda et al., J Urol. 1994 Mar;151(3):622-8, in view of Savarese et al., Prostate. 1998 Feb 1;34(2):80-91, and further in view of Thomas et al., Hum Gene Ther. 1998 Apr 10;9(6):835-43 is withdrawn because of applicant's persuasive arguments.

***Claim Rejections - 35 USC § 102***

Claims 35, 37, 38 and 40 rejected under 35 U.S.C. 102(b) as being anticipated by Wollin et al., Radiother Oncol. 1989 Jul;15(3):285-93, abstract only with this Office action. The full journal would be provided when available.

Claims 35, 37, 38 and 40 are drawn to a composition comprising a GM-CSF-expressing proliferation-incompetent PC3, or DU145.

Wollin et al., teach a composition comprising irradiated PC3, or DU145. According to either Lang et al., International Journal of Cancer 59 (2): p235-241 1994 abstract only, or Rockhlin et al., Anticancer Research ( ANTICANCER RES. ) (Greece) 1996, 16/2 (557-563 abstract only, both PC3, or DU145 expresses GM-CSF. As for the limitation "proliferation-incompetent", the specification at page 9 lines 12-15 discloses "proliferation- incompetent" refers to cells which are unable to divide, but which express genes encoding tumor associated proteins, and the instant specification at page 64, line 28 for example, discloses "irradiated" prostate cell lines before administration. Thus, the instant specification as a whole teaches that irradiation makes tumor cells "proliferation-incompetent". As for in vivo immune responses with the various molecular

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weights, the instant claim 35 says that a composition comprising irradiated PC3, or DU145 has the ability to produce such response.

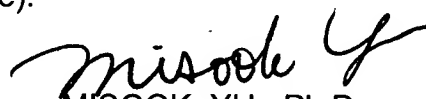
***Conclusion***

The objected claims are objected because they depend on the rejected base claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
MISOOK YU, Ph.D.  
Primary Examiner  
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